STATEMENT

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I. INTRODUCTION

Mr. Chairman, thank you for the opportunity to testify on reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA) and other issues relating to the Food and Drug Administration's (FDA) regulation of drugs and biologics.

FDA's primary mission for 90 years has been to promote and protect the public health. That remains our core mission. Each year FDA's responsibilities involve more than $1 trillion worth of products, many of which are vital for human health and sustenance. Our diverse activities include, but are not limited to, reviewing, approving, and monitoring the manufacture and use of prescription drugs, generic drugs, animal drugs, vaccines, biologics, medical devices, food additives and color additives; licensing blood banks; monitoring clinical investigations; inspecting food manufacturers; monitoring imported products; accrediting mammography facilities; and assuring the safety of cosmetics.

I know you share our view that all Americans expect and deserve the assurance that the medicines they take or the medical devices they use are safe and really work and that the foods they eat are safe, wholesome, and properly labeled. The assurance that FDA is

vigilant and active, every day, is so fundamental to our expectations of public health protection that it is almost taken for granted. Because of the protections in the food and drug laws, and the Agency's implementation of those laws, Americans do not worry about the safety or effectiveness of literally thousands of products they use every day, from breakfast cereal to pain relievers, from contact lenses to vaccines.

For more than nine decades, we have been protecting consumers against an ever-growing number of public health risks. At the same time, we have been providing the framework through which citizens have the opportunity to benefit from new, and often better, products. In doing so, we face many challenges: keeping pace with unprecedented medical and scientific breakthroughs; an ever-expanding workload; evolving expectations regarding consumer access to meaningful health information; and the globalization of manufacturing, trade, and consumption. An important measure of our value as an Agency, and of our success at fulfilling our mission to promote and protect the public health, has been our ability to meet these challenges. Utilizing this measure, I believe we have done very well.

At the same time, we have become keenly aware of how important it is to be innovative and self-critical. We recognize that the

industries we regulate have important contributions to make to public health and operate in a dynamic and demanding marketplace. We recognize that consumers are concerned with the timeliness as well as the thoroughness of Agency actions. Members of this Subcommittee and others in Congress critically reviewed the Agency's performance, and we appreciate the leadership of this Subcommittee on these issues. Our internal assessments also revealed the need for changes, and the Administration's Reinventing Government initiative required that we address outdated or unnecessarily burdensome regulatory practices. We want you to know that we heard the messages, and we set about addressing the problems. There is much work still to be done. Please know that the Agency, the Department of Health and Human Services, and the Administration are committed to working with Congress on bipartisan legislation that will help us do our job of promoting and protecting public health as well as we can.

I want to thank the Subcommittee for the opportunity to present an update on the substantial progress FDA has made over the past several years in improving its performance in the area of drugs and biologics and to share with you some of the problems we are working on and some others we need your help to address. If we are to focus our energies, as we must, on continuing to improve our efficiency and effectiveness, it is imperative that we

understand what currently is working well and what problems must be addressed.

I will describe some of the things we have done and the impact these efforts have had on our ability to function more efficiently and effectively. I will focus on three areas: drug review times; regulatory streamlining; and management reforms. I will then address the key problem areas the Agency is now confronting.

II. IMPROVING DRUG REVIEW TIMES

No area of FDA's responsibility has been more closely scrutinized by Congress, industry, health professionals, and the public than the approval process for new drugs, or more specifically, the speed with which new therapies of proven effectiveness and safety are made available to those who need them. For years there has been public discussion of the so-called "drug lag," the concern that new therapies were consistently being approved in Europe more quickly than in the United States. Today we are approving drugs in time periods that are as fast or faster than any country in the world with a comparable system of scientific rigor and public health commitment. We are doing it while maintaining the

traditionally high standards for safety and efficacy that make FDA approval the standard for the world.

Let me begin by citing our most important results last year under PDUFA. As you know, PDUFA provides additional resources linked to our commitment to meeting demanding review goals without sacrificing high public health standards. PDUFA was an experiment designed by Members of this Committee, representatives of the drug industry, and FDA in 1992. This important five-year authorization will expire in October.

Under PDUFA we are making decisions on breakthrough drugs in six months or less, and on all other drugs in 12 months or less. The Agency consistently has met its annual performance goals. In fact, we have exceeded them in almost every goal category. When combined with our internal management initiatives, the additional resources provided by PDUFA bring important products to patients more quickly and without sacrificing appropriate medical review. Last year's record of drug approvals by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) illustrates this.

The Agency's obligation is to make decisions on time. But a decision does not mean the drug is approved and available to

patients. Therefore, it is also relevant to look at the number of products approved and the time to approval. The record here is extraordinary. As compared to the Agency's performance prior to PDUFA, last year the Agency approved twice as many drugs in half the time.

All drugs approved by FDA are important, but none are as meaningful in bringing hope to patients as new molecular entities (NMEs). These are new medicines that have never been marketed before in this country. The number of NMEs approved each year is regarded as a real indication of meaningful medical progress. Last year, that progress was exceptional: FDA approved 53 NMEs, the most ever and nearly twice as many as any year before.

Let me put last year’s figures into perspective by referring back to the passage of the Kefauver-Harris amendments in 1962. The average annual total of NMEs in that decade was 13.7. In the 1970s, the corresponding figure went up to 17.3. In the 1980s, the average was 21.7 NMEs, and in the first half of this decade, the average was 25.6 NMEs. That is less than one-half of the 53 NME approvals last year.

Also, last year's approval times were much faster than in the past. In the late 1980s, median times to NME approval approached 30 months. The median time to approval for the 53 drugs approved in calendar year 1996 was 14.3 months, less than half the time it took as recently as the late 1980s. **[Chart 1]**

The NMEs approved by FDA in 1996 were not limited to one area--they covered a spectrum from cancer, to asthma, to Alzheimer's Disease, to multiple sclerosis. New cancer drugs approved last year were notable for their effectiveness against a broad spectrum of cancers: Hycamtin is used for the treatment of patients with metastatic carcinoma of the ovary; Camptosar for those with colorectal cancer; Taxotere for women with advanced breast cancer; Gemzar for patients with cancer of the pancreas; and Nilutamide for men with cancer of the prostate. The NME category also included Accolate, the first of a new class of drugs for asthma; Aricept, the second treatment for Alzheimer's disease; and Copaxone, a treatment of relapsing-remitting multiple sclerosis.

Several of the NMEs approved last year, including two drugs for cancer and three for HIV, were approved in six months or less. Crixivan, a protease inhibitor for the treatment of HIV, was approved in just 1.4 months. Twelve of the NMEs, including three

protease inhibitors, were developed--from the first commercial Investigational New Drug submission to marketing approval--in less than six years. The Agency and industry should look to the development of these products as models to be emulated for future drug development.

CBER also had a productive year. Last year it completed 17 major biological approvals, as compared with 12 such approvals the year before. Last year's major biological approvals included RespiGam, the first medication to protect infants against respiratory syncytial virus, a potentially fatal disease; Avonex, the second interferon product for multiple sclerosis; and Verluma, a new diagnostic imaging agent that can determine the extent of small cell cancer in different parts of the body at one time. The median approval time for the 17 biological products was 14.9 months, 15 percent faster than in 1995.

Moreover, the total number of new drugs and biological products--including NMEs, new dosage forms, etc.--approved in the last calendar year was 139, which is 63 percent more than the total the year before. **[Charts 2-3]** New Drug Applications (NDAs) accounted for 131 of these products and their median time to approval was 15.4 months, 7 percent faster than the 16.5 months the year before.

Another highlight of 1996 was the approval of 118 efficacy supplements for drugs. This is a 146 percent increase over the yearly number of approved drug efficacy supplements in 1993, the first year of PDUFA. Most importantly, the median total time to approval for these supplemental drug applications decreased 27 percent over the same period. **[Chart 4]** For biologics, the number of efficacy supplements rose from four to eleven (a 36 percent increase). The median total time to approval decreased 63 percent from 34 months to 12 months.

The Agency also continued to make significant progress in ensuring that over-the-counter drugs are safe and effective. In fiscal year 1996, 19 new drugs or indications for an existing drug were approved for over-the-counter (OTC) marketing. These applications are subject to PDUFA user fees. These approvals included opthalmics and oral drugs to treat allergy symptoms, cold remedies, new drugs to treat heartburn, ketoprofens to treat adult pain and reduce fever, antifungals to treat vaginal infections, nicotine gums and transdermal patches to help consumers quit smoking, and hair growth treatments for treating hereditary pattern baldness in men and women.

All of this suggests that American patients are getting the medications they need faster and more efficiently. Indeed, the

most recent international data confirm this. At the end of last year we looked at the new centralized drug approval process of the European Union--the system that is said by some to be better than ours. We looked at the 15 new drugs that had been approved both by FDA and the European Union centralized procedure. Overall, the United States approved them faster than the European Union. The median time for FDA review and marketing approval in the United States, for those 15 common drugs, is 5.8 months. The median time for review by the Committee for Proprietary Medicinal Products and final EU authorization for a company to sell those 15 common drugs in Europe is 12.2 months. Sometimes drugs are not submitted at the same time, and it is possible that the United States could be faster and American patients still be waiting. But that is not the case for these 15 drugs. In 11 instances, the drugs were first approved in the United States and, in four instances, the European Union authorization came first (by only three days in one instance).

Of particular note, according to the January 1997 issue of Scrip Magazine, more pharmaceutical companies chose the United States in 1996 for the introduction of their NMEs into market than any other country. There were 16 introduced in the United States (as compared to eight in Japan, seven in UK, six in Germany, and three in Denmark).

Consistent with the recommendations of the Vice President's 1993 National Performance Review report, the FY98 budget proposes $236,813,000 in reauthorized and new user fees to finance FDA activities, approximately $91,000,000 of which represent PDUFA reauthorization. Combined with the $7,459,000 in fees already authorized for export certification and the certification of insulin and color additives, the proposed Fiscal Year (FY) 1998 user fee level is $244,272,000. Specifically, the budget proposes to reauthorize PDUFA and MQSA and to collect new fees in each of the major programs. These fees will be dedicated to FDA program activities and will be implemented in conjunction with performance measures and goals.

The Agency's record of drug approvals illustrates why reauthorization of PDUFA is a top priority for FDA, industry, and patient groups. It is essential that this reauthorization happen quickly. PDUFA will expire at the end of this fiscal year (September 30, 1997). If the Agency receives no assurance by July 1 that PDUFA will be reauthorized, we will have to take certain steps to begin dismantling the program which will require terminating the positions of a significant number of employees. Federal law requires us to notify affected employees by August 1 (5 U.S.C. §3502(d)(1)). The medical reviewers are well aware of these time constraints and, if PDUFA is not reauthorized in a

short time, many are likely to start exploring job opportunities outside of the Agency. This will be detrimental to the industry, the Agency, and most importantly, every American.

III. REINVENTING AND STREAMLINING THE REGULATION OF DRUGS AND BIOLOGICS

Not all of our improvements have been due to resources added by PDUFA. The Agency also has pursued and implemented more than thirty reinvention initiatives under President Clinton's and Vice President Gore's National Performance Review. These reinvention initiatives, along with the significant number of streamlining efforts undertaken by the Agency on its own, are indisputable evidence that the Agency has a deep commitment to improving our regulatory processes. I would like to describe several of the more significant initiatives and I have attached to my testimony an appendix that sets forth summaries of our efforts and accomplishments.

A. SCIENCE-BASED REFORM

1. Supplemental Applications and the New Use Initiative

The Agency's New Use Initiative, announced in March, focuses on helping new drug sponsors establish proof that their products are effective without excessive or redundant studies. The issue of what constitutes sufficient evidence of effectiveness has been debated for years by the Agency, the scientific community, industry, and others. Sound evidence of medical efficacy is a crucial component of the Agency's risk-benefit assessment for a new product or new use of an already-approved product. The need to adequately describe benefits and side effects represents a major component of drug development time and cost. We understand, as well, that drug sponsors may be reluctant to pursue applications for new uses because of concerns that such efforts are too burdensome and costly. We all recognize that the conduct of studies in excess of those necessary to demonstrate effectiveness and toxicities is undesirable and wasteful.

The methodologies underlying drug development and clinical evaluation have evolved significantly. To ensure that drug development programs can be targeted specifically to what is necessary to properly establish effectiveness and safety, and to illustrate how the submission of applications for new uses, in

particular, need not be unduly burdensome, the Agency released for comment the "Draft Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products" (the Evidence document). This document, the key element of the Agency's "New Use Initiative," articulates the Agency's view concerning the quantitative and qualitative standards for demonstrating effectiveness of drugs and biologics. In addition to helping sponsors target drug development efforts, this articulation of policy will assure greater consistency and predictability to FDA's assessment of clinical trial data submitted in support of drug effectiveness.

At the same time the Agency released the Evidence document, it also released a second draft guidance document for public comment, "Guidance for Industry: FDA Approval of New Cancer Treatment Uses for Marketed Drug and Biological Products," illustrating the applicability of the principles set forth in the Evidence document specifically to new uses for drug products to treat cancers. A significant percentage of drugs used to treat cancer patients are used "off-label." That is, they are used for purposes for which they have not been specifically reviewed. The high incidence of off-label use of anti-cancer and other types of drugs is problematic in several respects. For example, we know

that many off-label uses are incompletely studied and that some off-label uses are not sufficiently safe and effective.

On the other hand, when such uses are properly studied and disseminated, this information should be made available widely to the health care community and the public. The best result for health care practitioners and patients would be for these uses to be described in the approved labeling. In other words, FDA should review the data to determine the magnitude of benefits and toxicities. This best case scenario will occur, however, only if the Agency has an effective supplemental application process and only if industry submits these applications. The requirements for what constitutes appropriate evidence of effectiveness must be clear and reasonable, and such applications must be reviewed expeditiously. We believe that this draft guidance document will help to make the supplemental application process a more useful and effective tool for getting additional uses in the labeling of drugs and biologics.

2. Regulation of Therapies Derived From Human Cells and Tissue

Perhaps no area of Agency responsibility has been more significantly affected by our reinvention initiatives than the

regulation of biologics. In January, we announced a new regulatory framework for therapies derived from human cells and tissues. This framework was developed based on scientific considerations after extensive discussions with industry, academics, and professional groups. It provides a tiered approach with the level of regulation proportionate to the degree of risk. Little or no regulation would be imposed on some products, with the degree of oversight increasing with the potential risk, so that extensively processed and novel products would require FDA's approval before they could be marketed. All tissue processing facilities would be required to register with FDA and to list their products, and all labeling and promotion of these products would have to be clear, accurate, balanced, and non-misleading.

This proposal has been well received and we expect it will be improved through the further input we expect to receive during the comment period.

B. PROCESS REFORMS

The foundation on which, in my view, all of the Agency's efforts to improve performance stand is effective management of all our processes. Effective management is the vehicle that turns the

written formulation or promise of reform into tangible outcomes that have measurable impacts on promoting and protecting public health. Process management is the tool through which our commitment to do better translates into improved performance. Some of the management improvements we have undertaken have contributed to the improved product approval times referenced in the first section of this testimony. Our efforts in this regard, however, have not been limited to the product approval programs. Effective management reforms have been a particularly important focus in all parts of the Agency. I would like to describe several of these initiatives.

1. Team Reviews/Project Management

In late 1993, both CDER and CBER established team-based project management programs designed to improve the quality and efficiency of the drug review process. Since that time, these programs have demonstrated their effectiveness and continue to be refined and enhanced.

Team-Based Project Management is a powerful technique combining the use of multidisciplinary teams led by project managers and scientific leaders who utilize the tools and techniques of project and resource tracking. Review disciplines are organized

into multidisciplinary teams early in the review process (within 45 days of the receipt of an NDA) to develop a review plan and commit to target interim and milestone completion dates. Teams meet periodically to exchange information, discuss significant aspects of the applications, review progress toward meeting target completion dates (PDUFA performance goals), and make resource adjustments. Consequently, a proactive management approach is employed in achieving the Centers' review performance goals.

Both Centers will be expanding use of these programs to encompass the Agency's activities in other areas such as the pre-investigational, investigational, and post marketing phases of the product development process. Our intent is to ensure that sponsors have a better understanding of the Agency's expectations for the review process at each stage of drug development.

Another example of process improvement resulting from, and contributing to, the culture of continuous quality improvement is the formulation of Good Review Practices (GRPs). CDER and CBER are implementing the GRP initiative because the organizations recognize the importance of training their reviewers. This initiative is designed to enhance the clinical review practices of CDER and CBER reviewers by standardizing review procedures and

providing a mechanism for ongoing feedback. The result will be practices, analogous to the good manufacturing practices (GMPs) prescribed for industry, that reflect the most current trends in drug and biologic review. Implementation of GRPs will improve the consistency, efficiency, and quality of reviews, as well as promote the science of regulatory review that is responsive to evolving technologies.

2. Application Harmonization

The Agency is pursing the harmonization of marketing applications for drugs and biologics. This will allow companies that manufacture drugs submitted for review to CDER and biologics submitted for review to CBER to include the same type and amount of information for similar products. This harmonization effort began one year ago with the elimination of the establishment license application for biologics. Further efforts are underway and are a top priority for CDER and CBER.

3. Guidance Documents

One of the themes that runs throughout the Agency's efforts to improve its performance is the importance of involving all stakeholders both in defining the problems that exist and in

developing appropriate solutions. This model of public participation, reflected in so many of the initiatives I have been discussing, is most clearly delineated in the procedures the Agency has promulgated for the issuance and use of Agency guidance documents. Concerns about the absence of public input on guidance documents and the inappropriate application of such guidance were raised in a Citizen’s Petition filed by the Indiana Device Manufacturers Council and were the subject of a hearing chaired by Congressmen Shays and McIntosh. In response to these concerns, the Agency undertook a thorough review, across all Agency components, of guidance document procedures. We found inconsistencies and lack of clarity, and we set about to fix them. The result is a new set of procedures, "Good Guidance Practices," that now will be uniformly applied by every Agency component. The purpose of Good Guidance Practices is to ensure that: (1) Agency guidance documents are developed with adequate public participation, (2) guidance documents are readily available to the public, and (3) guidance documents are not applied as binding requirements.

4. FDA and the Global Marketplace: International Harmonization

The regulatory framework administered by FDA to provide public health and safety protection to American consumers is a model that many countries strive to emulate. At the same time, FDA recognizes that we operate in an increasingly more global, more interdependent market environment, and that American consumers can realize significant public health and economic benefits from efforts by FDA to share information, explore opportunities to collaborate on assessments and product reviews, and harmonize standards with our foreign counterparts. Growing demands on FDA's resources to assure the safety and efficacy of greater numbers of increasingly more complex products, produced both here and abroad, absolutely mandate that FDA seek ways in which we can share our regulatory workload while maintaining public health protection for American consumers. Science-driven harmonization can curtail duplication and thereby significantly reduce the cost of new drug development, in terms of the risks to which patients are exposed, experimentation with animals, regulatory costs to Government and costs to industry.

In recent years, we have put considerable effort into the work of the International Conference on Harmonization (ICH), working

closely with our regulatory counterparts in Japan and the European Union, as well as the three areas' organizations representing major research and development pharmaceutical companies (e.g., the Pharmaceutical Research and Manufacturer's Association (PhRMA)). The goal of ICH is to harmonize across all three regions the requirements for data submitted to support safety, efficacy, and quality determinations in new drug applications, and to develop guidelines for industry based on the harmonized requirements. The past six years of effort have produced over 40 new harmonized guidelines, and another 20 are in various stages of development and review.

Additionally, for the past three years we have been involved in negotiations to give limited recognition to inspections of drug facilities by European Union authorities. A successful agreement has the potential to save resources for both sides; however, FDA must be satisfied that such an agreement would not compromise our responsibility for protecting American consumers.

IV. EFFORTS DIRECTED TOWARD CONTINUING IMPROVEMENT

Earlier this year we began a dialogue with industry, patient, and consumer groups regarding the issues that have been raised and debated over the past several years in the context of FDA legislation. We began the process by asking ourselves and others what problems need to be solved in order to do our job more efficiently and effectively. By defining problems first, we hope to ensure that proposed solutions will enhance our performance.

During the months of January, February, and March, the Agency participated in a number of meetings with groups representing the drugs and biologics industries, and with patient and consumer groups to discuss their issues of concern. Our meetings with industry were structured so that Agency staff with technical expertise in relevant areas worked with technical experts from industry to identify problems and discuss proposed solutions. It was useful to have technical experts work together because they deal with relevant issues on a regular basis and are best equipped to understand the problems and to develop and evaluate proposed solutions. I would like to spend a few minutes today discussing the substantial progress made during those meetings.

The first point I will make about those meetings is that we discovered strong agreement that the high standards we apply in our work must be maintained and that our limited resources should

be devoted to activities of sufficient public health importance to justify expenditures of both public and private resources. In other words, there must be tangible public health benefit from what we do and what we require.

There is also agreement that there may be ways to improve and streamline what we do as an Agency. The drugs and biologics industry groups identified a number of areas that they believe should be changed. For example, they believe that FDA requires the submission of unnecessary paper copies with drug applications and that this results in the submission of much unnecessary data. FDA agrees that it often receives unnecessary data and that the drug application should be examined to determine whether certain parts can be eliminated. The technical experts working on this issue have begun to evaluate whether summaries of certain types of trials can be submitted and whether any parts of the drug application can be eliminated.

The drugs and biologics industries also focused on issues relating to when a manufacturer has to get Agency approval of manufacturing changes, dispute resolution, the use of advisory committees, a mission statement, and the Agency's development and use of guidance documents. The industry and the Agency were able to agree on the problems to be addressed in each of these areas

and, in most instances, were able to agree on a framework for a solution. There are still issues to be resolved, but we believe that we have made substantial progress. The industry and FDA also began to discuss issues relating to information dissemination, pharmacoeconomics, and pediatric labeling. These discussions are still in the early stages.

A top priority for the patient and consumer groups is "sunshine." They argue that patients need access to more information about investigational drugs, clinical trials, and new drug applications. FDA also would like to be able to make more information about drugs under development and review available to patients.

Some of the proposed solutions being discussed by FDA, industry, and patient and consumer groups are administrative and others are legislative. The Agency believes that it is important to distinguish between when a statutory change is needed to effect a change, when a statutory change is merely desirable to ensure a change, and when an administrative change is the best option because the amount of detail involved is inappropriate to include in the statute.

During our discussions with the industry, patient, and consumer groups, the Agency identified a number of new issues that we believe also are important to more efficient and effective performance. I will spend a few minutes touching on a few of these issues. Some of the issues we raised relate to harmonizing the statutory provisions that apply to the different types of FDA-regulated products--particularly where there is no reason for the difference other than the fact that the provisions were passed at different times. For example, when the device law was passed, Congress saw fit to provide for civil money penalties and recall authority. The drug law, which was passed years earlier, did not include these tools. There is no reason not to have the same effective tools for devices and drugs. Just last year, Congress passed pesticide legislation that included a provision for civil money penalties.

Other issues raised by the Agency respond to the changing marketplace. For example, we want to discuss extending our explicit records inspection authority for OTC drugs. Under current law, FDA can inspect a facility that manufactures OTC drugs, but it lacks the explicit authority to inspect certain records of OTC drug facilities. This compromises the Agency's ability to detect problems that occur during the manufacturing of OTC drugs. The Agency can be certain of detecting those problems

only if it inspects the facility often enough to see them happening. The number and complexity of OTC products have increased tremendously over the past few years and we believe that consumers should have the same assurances of OTC drug quality that they have for prescription drug quality.

Finally, we would like to explore a number of measures that we believe will have wide support. These include the elimination of some very specific prescription drug labeling requirements, elimination of the prohibition on describing products as having FDA "approval," and creation of a risk-based time-frame for inspections. Under current law, FDA is required to inspect firms every two years. We are proposing to change this so that low risk products or firms would be inspected less often than high risk products or firms.

Mr. Chairman, I believe that the results of the discussions between FDA, industry, consumer, and patient groups will prove helpful to this Subcommittee as you move forward on issues relating to FDA legislation. We look forward to working with you on these very important issues.

V. CONCLUSION

Two years ago President Clinton explained the guiding philosophy in our examination of how we are performing: "protect people, not bureaucracy; promote results, not rules; get action, not rhetoric." That is what we have been trying to do. We are working hard to make FDA more efficient and to maintain the high quality of work.

The two pillars of FDA's success, and the reasons we have the confidence of the American public, are our independent public health commitment and scientific expertise. In the end, it is FDA's independence that gives the American people confidence in the Agency's decisions. They know that when FDA approves a drug, that approval is made free of commercial interests. While we recognize that it is important to work with industry and consumers to bring the best expertise to bear on problems, we must not overlook the importance of making regulatory decisions in an environment without bias or vested interest.

The second pillar--scientific expertise--is equally important. Some of the leading experts in the relevant scientific disciplines work for FDA. This is one of the reasons that drugs

approved in this country are an immediate international success.

We look forward to working with you to ensure that FDA meets our expanding and challenging mission in the most efficient and effective manner possible.